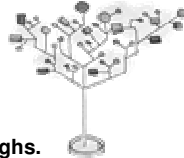




Licensing Intellectual Property Rights From The NIH

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Transfer

Technology Transfer Workshops & Symposium
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Science. Ideas. Breakthroughs.

NIH Technology Transfer Mission

- Uncover new knowledge that will lead to improved public health
- Identify, evaluate, protect, market and license technologies to achieve Agency mission
- Monitor progress and administer royalty payments
- Utilize intellectual property rights appropriately as incentives for commercial development
- Attract new R&D resources
- Stimulate economic development

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Overview

- NIH Technology Transfer Mission
- NIH Product Licensing Principles
- Portfolio of Licensable Technologies
- NIH License Application
- Types of Agreements
- Selected Agreements
- Exclusive Licensing Criteria
- Final Thoughts

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NIH Product Licensing Principles

- Maximize development of products for public health
- Ensure appropriate return on public investment
 - Grant only the appropriate scope of rights
 - Specific field of use
 - Prefer non-exclusives
 - Permit research uses
 - Ensure broad use of technology
 - Enforceable milestones and benchmarks

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Portfolio of Licensable Technologies

- Novel, fundamental research discoveries
- Early stage
- Selected technologies in early clinical studies
- Research Tools
- Representative of broad spectrum encompassing:
 - Infectious Diseases
 - General Medicine
 - Cancer
 - Medical Engineering

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Types of Agreements

- Research/Internal Use
 - Biological Materials License Agreement for Internal Use (unpatented materials)
 - Commercial Evaluation License Agreement (limited-term evaluation)
 - Non-Exclusive Patent License Agreement for Internal Commercial Use (no right to sell or otherwise distribute materials)

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NIH License Application

- Contact Information
- List of IP (and Materials)
- Type of Agreement
- Proposed Field of Use, Duration
- Research and Commercial Development Plan
- Signatures and Dates

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Types of Agreements

- Commercial
 - Non-Exclusive Patent License Agreement
 - Co-Exclusive Patent License Agreement
 - Exclusive Patent License Agreement
 - Non-Exclusive Biological Materials License Agreement (unpatented materials)
- Special
 - Inter-Institutional Agreement
 - Interference or Dispute Settlement Agreement

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Selected Agreements

- Typical Internal Use License
 - Non-Exclusive
 - Materials provided/screening not permitted
 - No reach through rights to products
 - Usually up front payments or annual fees

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Selected Agreements

- Typical Exclusive License
 - If required for development
 - Detailed development plan with benchmarks
 - Preference for capable small firms
 - CRADA research separate from license
 - U.S. manufacturing for U.S. product sales

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Selected Agreements

- Typical Commercial Evaluation License
 - Non-Exclusive
 - Materials provided/screening not permitted
 - Feasibility testing only
 - Short term (< 18 months)
 - Usually up front payments at modest cost

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Selected Agreements

- Typical Exclusive License
 - Substantial upfront fees
 - Moderate earned royalties
 - Appropriate benchmark payments
 - Share of sublicensing considerations
 - "White Knight" provisions

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Statutory Criteria for Assessing Exclusive License Request

- Interests of US Federal Gov and public will be best served
- Desired practical application of technology has not been achieved and may not be achieved under a non-exclusive license
- Required to attract investment capital or to justify capital expenditures
- Proposed terms and exclusivity will not be greater than necessary to bring technology to practical application
- Competition in market place will not be substantially reduced

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Procedural Criteria for Reviewing Exclusive License Applications

- Publish Intent to Grant Exclusive Notice in Federal Register for Period of 60 days
 - Opportunity for others to comment and/or object
 - Viable objection - written letter detailing the nature of the objection (followed by a completed license application) or a completed license application received by OTT before the end of Notice Period
- Competing Applicants:
 - Carve out Field of Use/Indication
 - Carve out specific Territories commensurate with IP application/coverage
 - Grant Co-Exclusives
 - Deny Objector's License Application
 - Grant Exclusive to Objector and Deny Original Applicant

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Procedural Criteria for Assessing Exclusive License Applications

- Evaluate Application based on:
 - Proposed Field of Use and its availability
 - Proposed Research, Development and Commercialization Plan and Market Analysis
 - Prospective Licensee's Infrastructure, FTEs, Financial Position, Core-Competency and Commitment to bring Product and/or Service to Market
 - Statutory Criteria

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Objections/Appeals

- Request for reconsideration must be submitted to the OTT Director within 30 days
- Ad hoc review committee appointed by OTT Director recommends decision within 45 days
- OTT Director's Final Determination to Applicant within 60 days
- Judicial review as the law permits
- Objector may appeal to NIH Director within 30 days
- NIH Director may appoint individual or committee as deemed appropriate
- NIH Director's Final Agency decision to Appellant within 60 days
- Judicial review as the law permits

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Awarding Exclusive Licenses

- No objections received or objection resolved, review activities during Notice Period, consult with IC and make Final Determination
- Finalize license negotiations
- ~10% of OTT executed agreements are exclusive

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Thank you!

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Final Thoughts

- Mission Driven – to Benefit Public Health
- Goal – Appropriate Transfer of Technology through Licensing
- Case Specific and Flexible
- Fair Return on Investment
- Win-Win Approach – We Want to Share in Your Success

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